AMENDMENTS TO THE CLAIMS

1. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:

(a) a controlled release core comprising: i) a core comprising at least one pharmaceutically acceptable excipient and only one active drug that consists of metformin hydrochloride; and ii) a sustained release coating surrounding the core;

(b) optionally a first seal coating surrounding the sustained release coating that does not contain an active pharmaceutical ingredient and that rapidly disperses or dissolves in water and

(c)~~(b)~~ an immediate release layer surrounding the sustained release coating of the controlled release core or the first seal coating if present comprising pioglitazone hydrochloride ~~a thiazolidinedione derivative~~ wherein not less than 95 ~~85~~%, of the pioglitazone hydrochloride ~~thiazolidinedione~~ is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37°C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0, ~~wherein the thiazolidinedione derivative can be either pioglitazone or a pharmaceutically acceptable salt thereof~~ and after storage at 40°C and 75% relative humidity for three months, the total pioglitazone ~~thiazolidinedione~~ related compounds or impurities in the dosage form is not more than 0.6% as determined by high performance liquid chromatography and each individual pioglitazone ~~thiazolidinedione~~ related compound or impurity in the final dosage form is not more than 0.25% wherein the pioglitazone ~~thiazolidinedione~~ related compounds and impurities are:

(i) (+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-5-hydroxy-2,4-thiazolidinedione;

(ii) (z)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzylidene]-2,4-

thiazolidinedione;
(iii) (+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-3-[2-(5-ethyl-2-pyridyl)ethyl]-2,4-thiazolidinedione;
(iv) (+/-)-ethyl-2-carbamoyltio-3-[4-[2-(5-ethyl-2-pyridyl)ethoxy]phenyl-] propionate; and
(v) ethyl-3-p-[2-(5-ethyl-2-pyridyl)ethoxy]phenyl-propionate.

2-3. (canceled).

4. (currently amended) The pharmaceutical dosage form as defined in claim 1 wherein not less than 100%, of the pioglitazone hydrochloride ~~thiazolidinedione~~ is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.

5-14. (canceled).

15. (currently amended) The pharmaceutical dosage form as defined in claim 1 wherein the total pioglitazone ~~thiazolidinedione~~ related compounds or impurities are not more than 0.5%.

16. (canceled)

17. (currently amended) The pharmaceutical dosage form as defined in claim 15 wherein each individual pioglitazone ~~thiazolidinedione~~ related compound or impurity in the final dosage form is not more than 0.20%.

18. (currently amended) The pharmaceutical dosage form as defined in claim 17 wherein each individual pioglitazone ~~thiazolidinedione~~ related compound or impurity in the final dosage form is not more than 0.10%.

19. (original) The dosage form of claim 1 wherein said controlled release core is an osmotic tablet.

20. (currently amended) The dosage form of claim 19 wherein the osmotic tablet consists of:

(a) a core comprising:

(i) 50-98% of said metformin hydrochloride;

(ii) 0.1-40% of a binding agent;

(iii) 0-20% of an absorption enhancer; and

(iv) 0-5% of a lubricant;

(b) optionally an inner ~~a~~ seal coat surrounding the core; and

(c) a sustained release coating surrounding the core or the inner seal coat if present ~~membrane~~ comprising:

(i) 50-99% of a polymer;

(ii) 0-40% of a flux enhancer and

(iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the metformin hydrochloride.

21. (canceled).

22. (canceled).

23. (original) The dosage form of claim 1 wherein said core is substantially free from any gelling or expanding polymer.

24. (previously presented) The dosage form of claim 1 wherein said controlled release of said metformin hydrochloride provides a Tmax of 8-12 hours.

25. (currently amended) The dosage form of claim 1 wherein said release of the pioglitazone hydrochloride ~~thiazolidinedione derivative~~ provides a Tmax of 1-12 hours.

26. (currently amended) The dosage form of claim 25 wherein said release of the pioglitazone hydrochloride ~~thiazolidinedione derivative~~ provides a Tmax of 1-4 hours.

27-34. (canceled).

35. (currently amended) A pharmaceutical dosage form comprising:

(A) a controlled release osmotic tablet comprising:

i) a core comprising at least one pharmaceutically acceptable excipient and only one active drug that consists of metformin hydrochloride; and

ii) a sustained release coating surrounding the core wherein the controlled release osmotic tablet ~~that~~ exhibits the following dissolution profile when

tested in a USP Type 2 apparatus at 75 rpms in 900 ml of simulated intestinal fluid with a pH of 7.5 and at 37°C:

0-25% of the metformin hydrochloride is released after 2 hours;

10-45% of the metformin hydrochloride is released after 4 hours;

30-90% of the metformin hydrochloride is released after 8 hours;

not less than 50% of the metformin hydrochloride is released after 12 hours;

not less than 60% of the metformin hydrochloride is released after 16 hours; and

not less than 70% of the metformin hydrochloride is released after 20 hours; and

(B) optionally a first seal coating surrounding the sustained release coating that does not contain an active pharmaceutical ingredient and that rapidly disperses or dissolves in water; and

(C) an immediate release pioglitazone hydrochloride layer surrounding the sustained release coating of the osmotic tablet or the first seal coat if present that releases not less than 90% of the pioglitazone hydrochloride from the dosage form within 30 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0 and the dosage form contains not more than 0.25% of the following compounds:

(i) (+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-5-hydroxy-2,4-thiazolidinedione;

(ii)(z)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzylidene]-2,4-thiazolidinedione;

(iii)(+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-3-[2-(5-ethyl-2-pyridyl)ethyl]-2,4-thiazolidinedione;

(iv)(+/-)-ethyl-2-carbamoyltio-3-[4-[2-(5-ethyl-2-pyridyl)ethoxy] phenyl-]propionate; and

(v) ethyl-3-p-[2-(5-ethyl-2-pyridyl)ethoxy]phenyl-propionate.

36. (previously presented) The pharmaceutical dosage form as defined in claim 35 wherein not less than 95%, of the pioglitazone hydrochloride is released from the dosage form within 30 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.

37. (previously presented) The pharmaceutical dosage form as defined in claim 35 wherein not less than 100%, of the pioglitazone hydrochloride is released from the dosage form within 30 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.

38. (previously presented) The dosage form of claim 35 wherein said osmotic tablet core is substantially free from any gelling or expanding polymer.

39. (previously presented) The dosage form of claim 35 wherein the osmotic tablet core exhibits the following dissolution profile when tested in a USP Type 2 apparatus at 75 rpms in 900 ml of simulated intestinal fluid with a pH of 7.5 and at 37°C:

0-15% of the metformin hydrochloride is released after 2 hours;
20-40% of the metformin hydrochloride is released after 4 hours;
45-90% of the metformin hydrochloride is released after 8 hours;
not less than 60% of the metformin hydrochloride is released after 12 hours;
not less than 70% of the metformin hydrochloride is released after 16 hours; and
not less than 80% of the metformin hydrochloride is released after 20 hours.

40. (previously presented) The dosage form of claim 35 that contains not more than 0.2% of the following compounds:

(i) (+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-5-hydroxy-2,4-thiazolidinedione;
(ii)(z)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzylidene]-2,4-thiazolidinedione;
(iii)(+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-3-[2-(5-ethyl-2-pyridyl)ethyl]-2,4-thiazolidinedione;

(iv)(+/-)-ethyl-2-carbamoyltio-3-[4-[2-(5-ethyl-2-pyridyl)ethoxy]
phenyl-]propionate; and
(v) ethyl-3-p-[2-(5-ethyl-2-pyridyl)ethoxy]phenyl-propionate.

41. (previously presented) The dosage form of claim 35 that contains not more than 0.1% of the following compounds:

(i) (+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-5-hydroxy-2,4-thiazolidinedione;
(ii)(z)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzylidene]-2,4-thiazolidinedione;
(iii)(+/-)-5-[p-[2-(5-ethyl-2-pyridyl)ethoxy]benzyl]-3-[2-(5-ethyl-2-pyridyl)ethyl]-2,4-thiazolidinedione;
(iv)(+/-)-ethyl-2-carbamoyltio-3-[4-[2-(5-ethyl-2-pyridyl)ethoxy]
phenyl-]propionate; and
(v) ethyl-3-p-[2-(5-ethyl-2-pyridyl)ethoxy]phenyl-propionate.